5. 510(K) SUMMARY

APR 16 2007

Submitter/Contact Name:	Jeme Wallace
Address:	1620 Waukegan Rd., MPGR-AL McGaw Park, IL 60085
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Date Prepared:	01/12/07
Trade Names:	COLLEAGUE GUARDIAN Configuration Tool COLLEAGUE DL2 Event History Download Software Application
Common Names:	Software Accessories
Classification Name:	Accessories to Infusion Pump defined in 21 CFR 880.5725
Class:	II
Equivalent Predicate:	COLLEAGUE Volumetric Infusion Pump and Software Accessories, K041191 and K010566
Device Description:	The COLLEAGUE GUARDIAN Configuration Tool is a proprietary, Personal Computer (PC) based software accessory that is used to define, create and maintain the COLLEAGUE Personality Feature Sets, Labels and rule sets (COLLEAGUE GUARDIAN Configurations) associated with the COLLEAGUE GUARDIAN feature. This feature is a clinical support tool that allows the clinician to compare pump programming with hospital-defined guidelines at the point of care. If the clinician programs any values outside of the rule sets established by the hospital, an out-of-limits warning occurs. These Configurations, including Personality Feature Sets and associated Labels, can be transferred to or from a

COLLEAGUE pump. In addition, the Configurations may be saved in a COLLEAGUE GUARDIAN Configuration Tool file, allowing the use of this tool to create and update Configurations. The tool also allows confirmation of new or modified Configurations, copying of Configurations and printing of Configuration reports. The COLLEAGUE GUARDIAN Configuration Tool, as compared to manual entry, minimizes the potential to transcribe the wrong data value from paper documents.

All COLLEAGUE Volumetric Infusion Pumps have an Event History that stores the most recent 1,000 sequential pump events, such as key presses, alarms and alerts. The COLLEAGUE DL2 Event History Download Software Application facilitates the Event History download to a PC. These events may be viewed, printed and copied to the Windows Clipboard for pasting into other programs.

Indications for Use:

The COLLEAGUE GUARDIAN Configuration Tool is a proprietary, Personal Computer (PC) based software accessory that is used to define, create and maintain the COLLEAGUE Personality Feature Sets, Labels and rule sets (COLLEAGUE GUARDIAN Configurations) associated with the COLLEAGUE GUARDIAN feature. This software accessory can be utilized with product codes of the COLLEAGUE Volumetric Infusion Pump that contain the COLLEAGUE GUARDIAN feature.

The COLLEAGUE DL2 Event History Download Software Application is a proprietary, Personal Computer (PC) based software accessory. It provides access to event history information from all product codes of the COLLEAGUE Volumetric Infusion Pump, which can then be downloaded, viewed, printed and copied to the Windows Clipboard for pasting into other programs.

Summary of Technological Characteristics:

The main features of the COLLEAGUE GUARDIAN Configuration Tool are:

- Enter, edit and delete Labels
- Enter, edit and delete Personalities
- Set/clear Personality-Label associations
- Save COLLEAGUE GUARDIAN Configurations
- Confirm COLLEAGUE GUARDIAN Configurations
- Retrieve previously saved COLLEAGUE GUARDIAN Configurations
- Print reports
- Transfer approved COLLEAGUE GUARDIAN Configurations from the COLLEAGUE GUARDIAN Configuration Tool to the COLLEAGUE Volumetric Infusion Pump
- Transfer COLLEAGUE GUARDIAN Configurations from the COLLEAGUE Volumetric Infusion Pump to the COLLEAGUE GUARDIAN Configuration Tool

The main features of the COLLEAGUE DL2 Event History Download Software Application are:

- Downloading and viewing of event history information
- Copying of downloaded information to the Windows clipboard
- Printing of downloaded information

Non-Clinical Testing:

Non-clinical testing associated with intended use claims was performed according to the Baxter Healthcare Corporation Product Development Process.

Conclusions:

The proposed COLLEAGUE GUARDIAN Configuration Tool and the COLLEAGUE DL2 Event History Download Software Application have been verified against product

design requirements and validated against defined user needs/intended uses and instructions for use. This demonstrates that these COLLEAGUE pump software accessories are safe and effective in their use with the COLLEAGUE Volumetric Infusion Pump, and perform as well as or better than their predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Baxter Healthcare, Corporation
Mr. Jeme Wallace
Associate Director, Regulatory Affairs
Global Regulatory Affairs
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McGaw Park, Illinois 60085-6730

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Re: K070125
Trade/Device Name: COLLEAGUE GUARDIAN Configuration Tool; COLLEAGUE DL2 Event History Download Software Application
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 12, 2007
Received: January 16, 2007

Dear Mr. Wallace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

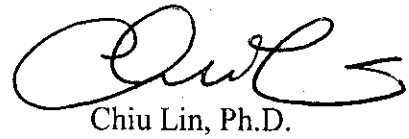
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): New Traditional 510(k)

Device Name: COLLEAGUE GUARDIAN Configuration Tool

Indications for Use: The COLLEAGUE GUARDIAN Configuration Tool is a proprietary, Personal Computer (PC) based software accessory that is used to define, create and maintain the COLLEAGUE Personality Feature Sets, Labels and rule sets (COLLEAGUE GUARDIAN Configurations) associated with the COLLEAGUE GUARDIAN feature. This software accessory can be utilized with product codes of the COLLEAGUE Volumetric Infusion Pump that contain the COLLEAGUE GUARDIAN feature.

Device Name: COLLEAGUE DL2 Event History Download Software Application

Indications for Use: The COLLEAGUE DL2 Event History Download Software Application is a proprietary, Personal Computer (PC) based software accessory. It provides access to event history information from all product codes of the COLLEAGUE Volumetric Infusion Pump, which can then be downloaded, viewed, printed and copied to the Windows Clipboard for pasting into other programs

Table 4-1.

Prescription Use: ☒	Over the Counter Use: ☐
21 CFR 801 Subpart D	21 CFR Subpart C

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] General Hospital,
[illegible]sion Contr[illegible] Devices

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